



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Donald L. Wise, Debra J. Trantolo, David D. Hile, and Stephen A. Doherty

Serial No.: 10/613,975

Art Unit: 1642

Filed: July 3, 2003

Examiner: Not Yet Assigned

For: *VACCINES TO INDUCE MUCOSAL IMMUNITY*

Commissioner for Patents  
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Alexandria, VA 22313-1450

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Pursuant to 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicants submit an Information Disclosure Statement, including eight (8) pages of Form PTO-1449 and copies of the sixty-eight documents cited therein.

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**U.S. Patents**

<u>Number</u>	<u>Issue Date</u>	<u>Patentee</u>	<u>Class/Subclass</u>
5,429,822	07-04-1995	Gresser, et al.	424/426
5,456,917	10-10-1995	Wise, et al.	424/426

### Publications

ALONSO, et al., "Determinants of release rate of tetanus vaccine from polyester microspheres," *Pharm. Res.* 10(7): 945-953 (1993).

ANCHORDOQUY & KOE, "Physical stability of nonviral plasmid-based therapeutics," *J. Pharm. Science.* 89(3): 289-296 (2000).

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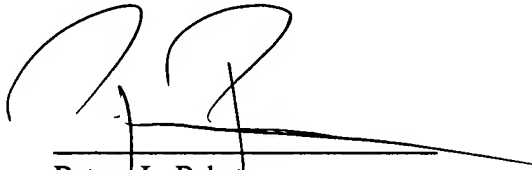
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U.S.S.N.: 10/613,975  
Filed: July 3, 2003  
INFORMATION DISCLOSURE STATEMENT

### Remarks

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,



Patrea L. Pabst  
Reg. No. 31,284

Dated: October 28, 2003

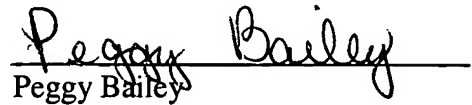
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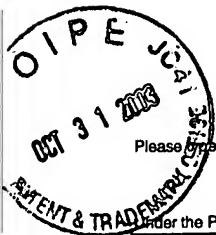
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				<b>Filing Date</b>	<b>July 3, 2003</b>
				<b>First Named Inventor</b>	<b>Donald L. Wise</b>
				<b>Group Art Unit</b>	<b>1642</b>
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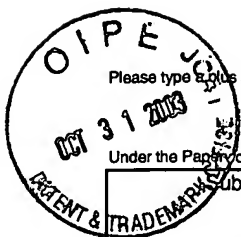
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		<b>Filing Date</b>	July 3, 2003		
		<b>First Named Inventor</b>	Donald L. Wise		
		<b>Group Art Unit</b>	1642		
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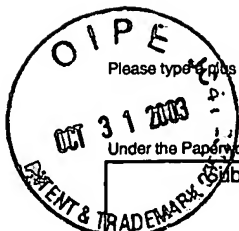
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				<b>Application Number</b>	
				10/613,975	
				<b>Filing Date</b>	
				July 3, 2003	
				<b>First Named Inventor</b>	
Donald L. Wise					
<b>Group Art Unit</b>					
1642					
<b>Examiner Name</b>					
<b>Attorney Docket Number</b>					
CSI 130					

Sheet	5	of	8
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		KLIMPEL, et al., "Anthrax toxin protective antigen is activated by a cell surface protease with the sequence specificity and catalytic properties of furin," <i>Proc. Natl. Acad. Sci., USA</i> 89: 10277-10281 (1992).	
		KLINMAN, et al., "Repeated administration of synthetic oligodeoxynucleotides expressing CpG motifs provides long-term protection against bacterial infection," <i>Infect. Immunol.</i> 67: 5658-5663 (1999).	
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		<b>Group Art Unit</b>	<b>1642</b>		
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		LUNS福德, et al., "Tissue distribution and persistence in mice of plasmid DNA encapsulated in a PLGA-based microsphere delivery vehicle," <i>J. Drug. Target.</i> 8(1): 39-50 (2000).	
		LUO, et al., "Synthetic DNA delivery systems," <i>Nature Biotech</i> 18: 33-37 (2000).	
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		O'HAGAN, et al., "Long-term antibody response in mice following subcutaneous immunization with ovalbumin entrapped in biodegradable microparticles," <i>Vaccine</i> 11(9): 965-969 (1993).	
		PARTIDOS, et al., "Mucosal immunization with a measles virus CTL epitope encapsulated in biodegradable PLG microparticles," <i>J. Imm. Meth.</i> 195: 135-138 (1996).	
		PEREZ, et al., "Poly(lactic acid)-poly(ethylene glycol) nanoparticles as new carriers for the delivery of plasmid DNA," <i>J. Control. Rel.</i> 75: 211-224 (2001).	

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		PERTMER, et al., "Gene gun-based nucleic acid immunization: elicitation of humoral and cytotoxic T lymphocyte responses following epidermal delivery of nanogram quantities of DNA," <i>Vaccine</i> 13(15): 1427-1430 (1995).	
		PRICE, et al., "Protection against anthrax lethal toxin challenged by genetic immunization with a plasmid encoding the lethal factor protein," <i>Infect. Immunity</i> . 69(7): 4509-4515 (2001).	
		SEDEGAH, et al., "Boosting with recombinant vaccinia increases immunogenicity and protective efficacy of malaria DNA vaccine," <i>Proc. Nat. Acad. Sci. USA</i> 95: 7648-7653 (1998).	
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		SMITH, et al., "Induction of secretory immunity with bioadhesive poly (D,L-lactid-co-glycolide) microparticles containing <i>Streptococcus sobrinus</i> glucosyltransferase," <i>Oral. Microbiol. Immunol.</i> 15: 124-130 (2000).	
		STOUTE, et al., "A preliminary evaluation of a recombinant circumsporozoite protein vaccine against <i>Plasmodium falciparum</i> malaria," <i>N. Engl. J. Med.</i> 336: 86-91 (1997).	
		THOMASIN, et al., "Tetanus toxoid and synthetic malaria antigen containing poly(lactide)/poly(lactide-co-glycolide) microspheres: importance of polymer degradation and antigen release for immune response," <i>J. Control. Rel.</i> 41: 131-145 (1996).	
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		TRANTOLO, et al., "Delivery of vaccines by biodegradable polymeric microparticles with bioadhesion properties," <i>Proc. 5<sup>th</sup> World Congress, Chem. Eng.</i> (1996).	

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		VISSCHER, et al., "Biodegradation of and tissue reaction to 50:50 poly(DL-lactide-co-glycolide) microcapsules," <i>J. Biomed. Mat. Res.</i> 19: 349-365 (1985).	
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		WEINER, "Oral tolerance," <i>Proc. Natl. Acad. Sci. USA</i> 91: 10762-10765 (1994).	
		WOLFF, et al., "Direct gene transfer into mouse muscle in vivo," <i>Science</i> 247: 1465-1468 (1990).	
		WU & RUSSELL, "Nasal lymphoid tissue, intranasal immunization, and compartmentalization of the common mucosal immune system," <i>Immunol. Res.</i> 16(2): 187-201 (1997).	
		YEE, et al., "Loss of either CD4 <sup>+</sup> or CD8 <sup>+</sup> cells does not affect the magnitude of protective immunity to an intracellular pathogen, <i>Fancisella tularensis</i> strain LVS," <i>J. Immunol.</i> 157: 5042-5048 (1996).	

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